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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/363,748	07/30/1999	CAROL WATKINS	108137.701	8501
27130	7590	12/03/2004	EXAMINER	
EITAN, PEARL, LATZER & COHEN ZEDEK LLP 10 ROCKEFELLER PLAZA, SUITE 1001 NEW YORK, NY 10020			CRANE, LAWRENCE E	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/363,748

Applicant(s)

WATKINS ET AL.

Examiner

L. E. Crane

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/25/04 RCE/Amdt.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims **1-53** have been cancelled, no claims have been amended, the disclosure has not been further amended, and new claims **54-61** have been added as per the amendment filed October 25, 2004. Under the authority of 37 C.F.R. §1.126 the last two new claims have been renumbered as -- **60** -- and -- **61** --, respectively. Applicant is respectfully requested to correct the record accordingly in all subsequent communications with the USPTO. No additional Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Claims **54-61** remain in the case.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claims **54-61** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims **54 and 59** the term “a derivative or metabolite thereof,” making reference to both uridine and cytidine in the noted claims, are functional terms which lack any limit on their scope. In light of the failure of the disclosure to provided a definition of the noted term, examiner finds that the noted term is inadequately supported by the written description and its deletion is therefore respectfully requested. See *Regents of the University of California v. Eli Lilly* (119F.3d 1559 at 1568; 43 USPQ2d 1398 at 1406 (Fed. Cir 1997)) which MPEP §2163 at page 2100-162, column 1, quotes as follows: “A definition by function alone ‘does not suffice’ to describe a coding sequence ‘because it is only an indication of what the gene does, rather than what it is.’”

Claims **54-61** are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **54** at lines 2 and 4, the term “a brain” incorrectly implies the possibility of multiple brains in the host. Examiner suggests that the noted term should read -- the brain -- in both locations. See also claim **59** at lines 2 and 5.

In claim **54** at line 2, the term "a subject" is incomplete. Examiner suggests that the term should read -- a subject in need thereof --. See also claim **59** at line 2.

In claim **54** at line 2, the term "a uridine" incorrectly implies the possibility of multiple different compounds. Examiner suggests that the term should read -- uridine --. The same criticism applies to the term "a cytidine" at line 3 of claim **54** and also claim **59** at line 4.

In claim **57** at line 1, the term "such as" is indefinite because the following list of uridine sources is not exhaustive and because the noted term causes the noted claim to lack adequately defined metes and bounds. In addition, because cytidine may be a uridine source via in vivo deamination the noted term expands the subject matter into subject matter specifically excluded by the disclosure at page 11, at lines 6-7.

In claim **58** at lines 1-2, the term "a uridine-5'-monophosphate" incorrectly implies the possibility of multiple different compounds. Examiner suggests that the term should read -- uridine -5'-monophosphate --. See also claim **61** at lines 1-2.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims **54**, **56** and **58-61** are rejected under 35 U.S.C. §102(b) as being anticipated by **Dawson et al.** (PTO-1449 ref. AI).

Applicant is referred to the abstract of the noted reference which discloses the administration of radiolabelled UMP to a mammalian host and the observation that radiolabelled CMP is found shortly thereafter within the tissues of the host.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

Claims **54-61** are rejected under 35 U.S.C. §103(a) as being unpatentable over **Dawson et al.** (PTO-1449 ref. **AI**) in view of **von Borstel et al. '838** (PTO-1449 ref. **AB**) and further in view of **Lehninger** (PTO-892 ref. **XA**).

The instant claims are directed to a method of increasing the level of "cytidine or a derivative or metabolite thereof" in the brain of a host by administration of "uridine or a derivative or metabolite thereof" in a mammalian host wherein the "uridine or a derivative or metabolite thereof" is administered orally as a supplement or as a component of a food.

Dawson et al. discloses that *in vivo* the administration of radiolabelled UMP to a mammalian host and the observation that radiolabelled CMP is found shortly thereafter within the tissues of the host.

Dawson et al. does not expressly disclose the administration of uridine or a uridine source orally or as a component of a food.

von Borstel et al. '838 at columns 2-4 makes repeated references to the oral administration of uridine and uridine monophosphate. In addition this reference at column 18, lines 39 et seq. discloses the oral administration of pharmaceutical compositions containing numerous different uridine derivatives.

And the **Lehninger** reference discloses that uridine/uridyate is well known in the art to be converted into cytidine/cytidylate in the normal course of nucleoside/nucleotide metabolism in living cells generally, which disclosure confirms the disclosure of **Dawson et al.**

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to orally administer uridine to a host in need thereof as taught by **von Borstel et al.** in the method taught by **Dawson et al.**

One having ordinary skill in the art would have been motivated to combine these references because all three references disclose closely related aspects of uridine/uridylylate administration.

Therefore, the instant claimed method of increasing the level of cytidine or derivatives or metabolites thereof in a host in need thereof by administration of uridine or a derivative or metabolites thereof would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

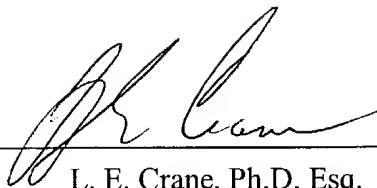
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

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LECrane:lec
11/22/2004

A handwritten signature in cursive script, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D. Esq.
Primary Patent Examiner
Technology Center 1600